

REMARKS

Response to Claim Objections

Claim 117 was objected to by the Examiner because of the following informalities: In claim 117, line 3, "is" should be "in" to correct a minor typographical error and in claim 117, the Examiner suggested that transverse dimension in the first configuration be qualified using "first" and the transverse dimension in the second configuration be qualified using "second" to avoid confusion.

In response, applicants have amended claim 117 as suggested by the Examiner.

Response to Claim Rejections Under 35 USC §112

Claims 1-20, 51, 74-79, and 89-93 were rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner contends that the recitation "so the head is retained by the posterior stopping surface of the stopping member" found in claim 1 introduces new matter.

Applicants disagree. The entire passage in claim 1 is "so that the head is retained by the posterior stopping surface of the stopping member within the transverse passageway between the biased stopping member and the second opening in the stabilizing element". The Examiner agrees that the stopping surface prevents the back-out of the screw or securing element and therefore would prevent the enlarged head from leaving the transverse passageway between the biased stopping member and the second opening in the stabilizing element or bone plate. As clearly shown in Figure 5 the small posterior opening in the stabilizing element prevents the enlarged head of the securing element from exiting the posterior bore portion posteriorly and the stopping

surface of the stopping member prevents the enlarged head of the securing element from exiting the transverse passageway anteriorly. In essence the head is retained within the passageway by the stopping surface of the stopping member and the posterior opening in the stabilizing element.

In column 3, lines 1-3, of the issued '291 patent the following statement is found

In the assembly of the invention, the securing element is prevented from backing out of the bone by the interaction of the securing element head and the stopping member.

In column 3, lines 16-23, of the issued '291 patent the statement is made

The orthopedic implant assembly of the invention can be durably attached to bone, and the securing element prevented from significantly backing out of the bone due to the head of the securing element being retained within the stabilizing element. (Emphasis Added)

Furthermore, as noted in Column 5, lines 25-30 of the '291 patent

Thus, the anterior surface of the head will butt up against the posterior surface of the collar without expanding the collar, to prevent the securing element from being anteriorly displaced out of the posterior section of the transverse passageway.

As shown in Figures 5, 10 and 14, the posterior stopping surface of the stopping member and the posterior opening prevent the enlarged head from being displaced from the posterior bore portion of the stabilizing element, i.e. they retain the head within the posterior bore portion. Therefore, it is clear that the posterior stopping surface of the stopping member facilitates retention of the head within the passageway as called for in claim 1. The fact that the small posterior opening would also facilitate retention of the head within the passageway, in no way negates the fact that the posterior stopping surface of the stopping member likewise facilitates retention of the head within the passageway.

The law is clear that the claim language need not be described *in haec verba* or

in *ipsis verbis* to meet the description requirement (§112(1)). *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 97 (CCPA 1976) *appeal after remand*, 646 F.2d. 527, 209 USPQ 554 (CCPA) 1981); *Fujikawa v. Wattanassin*, 93 F.3d. 1559, 1570, 39 USPQ 1895, 1904 (Fed. Cir.1996). Applicants submit that there is no question that the stopping surface of the stopping member at least in part retains the head of the securing member within the posterior bore portion, so this claimed feature of facilitating retention of the head within the posterior bore portion is adequately described in the specification and is therefore not new matter.

Applicants also believe that even the dictionary definition of the term “retain” (See the attached page 1213 of Webster. New World Dictionary attached as Exhibit A) supports applicants’ use of the term. See for example definitions 1 and 3, namely “to hold or keep in possession” and “to continue to have or hold in”. That is exactly what the stopping member does, it holds the head within the passageway.

Applicants submit that these claims comply with the written description requirement.

Claims 1-20, 29-31, 33-40, 42-51, 60, 63-79, 89-102, 104-106 and 114-119 were rejected by the Examiner under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends that the recitation “by the posterior stopping surface of the stopping member within the transverse passageway between the biased stopping member and the second opening in the stabilizing member” render the claim vague because it amounts to a double inclusion. While the applicants believe that it is clear that claim 1 includes only one stopping member and

that is the biased stopping member and that the stopping member has a posterior stopping surface that retains the head of the securing element within the posterior bore portion, nonetheless applicants have amended claim 1 to call for the stopping member in line 4 and line 7 of claim section c. to be “the stopping member” which refers back to the biased stopping member in claim section b. to avoid the possibility of vagueness. As to claims 29, 89, 94 and 96, these claims have been cancelled without prejudice. However, the new independent claims 120-126 and the prior claim 63 call for facilitating retention of the head of the securing member within the posterior bore portion. From the above discussion it is clear that stopping member facilitates retention of the head of the screw (along with the small posterior opening in the stabilizing element) within the passageway.

Response to Claim Rejections Under 35 USC §102

Claims 89-95, 115 and 116 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Dill (U.S. Pat. No. 5,118,235). Claims 89 and 94 have been cancelled and new claims 120 and 124 have been added. Applicants' new claims call for the stopping member to have a first configuration which is deformed elastically by the enlarged portion of the securing element to a second configuration to allow the enlarged portion to pass into the posterior bore portion. The stopping member then returns to the first configuration so that the posterior stopping surface of the stopping member prevents the enlarged portion from backing out of the posterior bore portion.

In comparison, the flap (90) of Dill is outside of the anterior bore portion in a first configuration in order to allow the screw head 24 to pass through the anterior bore portion to the posterior bore portion. Importantly, the flap (90) is not contacted by the

head and must be deformed by the operator. The flap is required to be pushed beyond the lip 80 by the operator in order to position the flap to prevent the screw head from backing out. The flap of Dill is not elastically deformed from the first configuration to the second configuration by the head of the screw as called for in the new claims 120 and 124. Dill therefore fails to teach all of the claimed features of new claims, so this reference cannot anticipate these claims as contended by the Examiner.

Claims 89-95 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Campbell et al. (U.S. Pat. No. 6,258,089). In reviewing Campbell et al. it was noted that there were basically three embodiments, one shown in Figures 1-24, one shown in Figures 25-27 and one referenced in column 8, lines 19-21 wherein the locking rim is elastically deformable rather than the head of the screw.

The embodiments shown in Figures 1-24 of Campbell et al. have been dismissed in the discussion herein because these embodiments require an additional instrument to move the stopping member after the head of the screw passes the stopping member. Moreover, the embodiments found in Figures 1-24 have other features which move these embodiments well away from applicants' invention.

The embodiment shown in Figures 25-27 of Campbell has a deformable head and while the deformable head has head elements (142) which are deformed from a first configuration to a second configuration by the locking rim, the deformed head elements of the Campbell et al. device do not return to the first configuration as called for in applicants' new claim 121, they remain deformed.

With respect to the third embodiment referred to in column 8, lines 19-21 but not shown in the drawings, the locking rim is elastically deformable and the head of the

screw is not. This would require the locking rim to deform upwardly and outwardly so the combined screw head and plate assembly would not look as it does in Figure 27. Importantly, the locking rim (stopping member) would not return to its first configuration after the head of the screw passes into the bore because the head is not deformable. As noted above, new claims 120, 122 and 125 call for the stopping member to be deformed by the head of the screw and to return to the first configuration after deformation. The Campbell et al embodiments do not do that.

With respect to applicants new claim 125, this claim calls for the stopping member to have a posterior stopping surface and the enlarged integral portion of the securing element to have an anterior surface which is configured to engage the posterior stopping surface after the enlarged integral portion passes the stopping member and the stopping member returns to the first configuration so as to prevent the enlarged portion of the securing element from backing out of the posterior bore portion and to facilitate retention of the enlarged integral portion within the posterior bore portion. The device described by Campbell et al. (Col. 8, lines 19-21) calls for a locking rim but the locking rim would not engage an anterior surface of the securing member.

It should also be noted as an aside that the same force used to push the head of the Campbell et al. screw within the bore of the bone plate could remove the head from the bone plate because there is no true locking function in the embodiment shown in Figs. 25-27 of Campbell et al. There is just merely resistance to moving within the passageway.

Conclusions

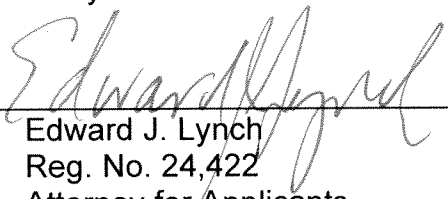
Applicants have included herewith a listing of all claims, including the claims

present in the original patent and a Mark-Up Of Amended Claims which indicates the changes made to the claims in the new amended claim pages.

Applicants have also included a chart pursuant to 37 C.F.R. §1.173(c) listing the status and support for the all claims not found in the issued patent and amendments thereto.

Applicants believe that the pending claims define patentable subject matter. Further consideration pursuant to the concurrently filed RCE is requested along with an early allowance.

Respectfully submitted:

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